

Voting Questions

Advanced Circulatory Systems Inc. ResQCPR System

The ResQCPR™ System is comprised of two devices: The ResQPOD® 16.0 Impedance Threshold Device (ITD), and the ResQPump® Active Compression Decompression CPR (ACD-CPR) Device. These devices are used together during manual CPR in an attempt to enhance venous return to the heart and blood flow to vital organs during CPR to ultimately increase survival and neurologic outcome in patient suffering from out of hospital cardiac arrest.

The sponsor has proposed the following Indications for Use:

The ResQCPR™ System is intended for use in the performance of CPR to improve the likelihood of survival with favorable neurologic function in adult patients with non-traumatic cardiac arrest.

The following questions relate to the approvability of the Advanced Circulatory Systems Inc. ResQCPR System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Voting Question 1:

Is there reasonable assurance that the ACSI ResQCPR System is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that the ACSI ResQCPR System is effective for use in for patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the ACSI ResQCPR System for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?